

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION**

In re: ZETIA (EZETIMIBE) ANTITRUST LITIGATION
This Document Relates To: <i>All Actions</i>

Case No. 2:18-md-2836

**GLENMARK DEFENDANTS' MOTION
FOR SUMMARY JUDGMENT ON ALL CLAIMS**

Exhibit 51

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA, NORFOLK DIVISION**

In re: ZETIA (EZETIMIBE) ANTITRUST
LITIGATION

MDL No. 2836

Civil Action No. 2:18-md-2836

CONFIDENTIAL

SUBJECT TO PROTECTIVE ORDER

EXPERT REPORT OF TODD CLARK, MBA, MS

January 13, 2020

other ANDA for 180 days from the date that the first filer commences commercial marketing of its ANDA product.³⁹ As a result, for six months following the first filer's commencement of commercial marketing (known as the generic exclusivity period), the first filer will be the only company able to sell an ANDA generic. However, during this exclusivity period, the brand may also choose to sell what is referred to as an authorized generic under the brand company's original NDA.⁴⁰ The first-to-file exclusivity allows the first-filing generic to capture a greater share of the market and charge a higher price during its first 180 days on the market than would be possible in the face of multiple ANDA generic entrants.

41. Brand and generic manufacturers will often settle Hatch-Waxman litigation. Sometimes, as part of the settlement, the brand manufacturer pays the generic manufacturer in order to preserve its patent exclusivity and avoid the risk of losing the patent case. Such settlements are referred to as unlawful reverse payment or pay-for-delay settlements.⁴¹ In this case, plaintiffs allege that Merck paid Glenmark to avoid the risk of generic competition by agreeing not to introduce an authorized generic version of Zetia.⁴²

42. Paragraph IV settlements may also contain "acceleration clauses," permitting the generic to launch at an earlier-than-agreed-upon date if another generic does so. In this case, such clauses were included in the settlements entered by, among others, Teva and Sandoz.⁴³

³⁹ Draft Guidance for Industry: 180-Day Exclusivity – Questions and Answers. Food and Drug Administration (January 2017),

⁴⁰ Draft Guidance for Industry: 180-Day Exclusivity – Questions and Answers. Food and Drug Administration (January 2017),

⁴¹ *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013)

⁴² Direct Purchaser Plaintiffs Consolidated Amended Class Action Complaint, at ¶ 4.

⁴³ MRKZETIA_R000048316, at 10-11, Section 5.2 (Sandoz); MRKZETIA000935898, § 5.2(B) (Teva).

Merck, but Merck did not sue Teva within the first 45 days.⁵³

54. [REDACTED]

[REDACTED] On September 1, 2010, Merck/Schering sued Teva for infringement of the '966 and '721 patents.⁵⁵ The parties settled, and the suit was dismissed on July 11, 2011, [REDACTED]

55. [REDACTED]

56. [REDACTED]

57. [REDACTED] Teva did not

⁵³ Teva-Zetia_00001054.

⁵⁴ Teva-Zetia_00001745.

⁵⁵ Teva-Zetia_00001903.

⁵⁶ MRKZETIA000935898.

⁵⁷ MRKZETIA000935898, § 5.2(B).

⁵⁸ Teva-Zetia_00001938.

⁵⁹ Teva-Zetia_00001951.

⁶⁰ Teva-Zetia_00003100.

2. The application from Sandoz was also likely to result in earlier generic entry.

63. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

64. [REDACTED] Merck sued Sandoz on the '106, '058, '966, and RE '461 (a reissue of the '721) on September 27, 2012.⁷⁵

65. [REDACTED]

[REDACTED]

66. [REDACTED]

[REDACTED]

67. [REDACTED]

[REDACTED]

⁷¹ SANDOZ-ZETIA-0000004.

⁷² SANDOZ-ZETIA-0000009.

⁷³ SANDOZ-ZETIA-0000009.

⁷⁴ MRKZETIA000932837.

⁷⁵ SANDOZ-ZETIA-0000011, at -024.

⁷⁶ SANDOZ-ZETIA-0000011.

⁷⁷ Merck Sharp & Dohme Corp., et al v. Sandoz Inc., No. 12-6077 (D.N.J.) [ECF No. 26].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

68. On September 9, 2013, the court entered Sandoz and Merck’s consent judgment ending their patent litigation.⁸⁰

69. [REDACTED]

[REDACTED]

70. [REDACTED]

[REDACTED]

[REDACTED] As we have seen, tentative approvals are issued when an ANDA “otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act” but cannot receive final approval because there are blocking patents or exclusivities.⁸⁴

71. [REDACTED]

[REDACTED] Sandoz

⁷⁸ MRKZETIA_R000048316.

⁷⁹ MRKZETIA_R000048316, at 10-11, Section 5.2.

⁸⁰ Merck Sharp & Dohme Corp., et al v. Sandoz Inc., No. 12-6077 (D.N.J.) [ECF No. 48].

⁸¹ SANDOZ-ZETIA-0000077.

⁸² SANDOZ-ZETIA-0000147.

⁸³ SANDOZ-ZETIA-0000081.

⁸⁴ 21 CFR 314.3(b).

⁸⁵ SANDOZ-ZETIA-0000081.

and that, as a rational generic manufacturer, Sandoz would have planned and prioritized accordingly and been ready, willing, and able to launch generic Zetia no later than February 16, 2016, or 180 days after the first filer's entry, if such date fell after February 16, 2016.

V. CONCLUSION

The FDA granted tentative approval for generic versions of Zetia from Teva on November 13, 2015 and from Sandoz on February 16, 2016. Prior content has established that:

- Tentative approval means that the FDA has determined that the drug is ready for commercial sale except for blocking patents or exclusivities;
- Generic drug makers receive substantial short and long-term benefits from launching their products as soon as possible, particularly for blockbuster drugs, and set their priorities accordingly;
- Neither Teva nor Sandoz had any known regulatory, capacity, or raw materials problems at any of the relevant facilities during the relevant time.

As such, it is my opinion that Teva and Sandoz would have obtained final approval and launched on or about their respective tentative approval dates if Glenmark and an authorized generic had launched at least 180 days before such dates, and that if Glenmark launched at some later point, Teva and Sandoz would have obtained final approval and launched on or about 180 days after Glenmark.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Todd Clark", with a horizontal line underneath it.

Todd Clark, MBA, MS

January 13, 2020